PATENT COOPERATION TREATY ax and post In JERNATIONAL PRELIMINARY EXAMINING AUTHORITY 15 MAR 2005 Gowling Lafleur Henderson LLP WRITTEN OPINION

CANADA (PCT Rule 66) (613) 563-9869 Date of mailing (day/month/year) 28.05.2004 Applicant's or agent's file reference **REPLY DUE** within 3 month(s) 08-892370WO from the above date of mailing International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/CA 03/00964 27.06.2003 28.06.2002 International Patent Classification (IPC) or both national classification and IPC A01H5/00, A01H5/00 Applicant UNIVERSITY OF GUELPH et al. This written opinion is the first drawn up by this International Preliminary Examining Authority. 1.

2.	This opinion contains indications relating to the following items:						
٠	1	\boxtimes	Basis of the opinion				
	II		Priority				
	Ш	\boxtimes	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
	IV		Lack of unity of invention				
****	٧	\boxtimes	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
	VI		Certain documents cited				
	VII		Certain defects in the international application				
	VIII		Certain observations on the international application				
3.	The applicant is hereby invited to reply to this opinion.						
	When?		See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).				
	How?		By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.				
•	Àlso:		For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an Informal communication with the examiner, see Rule 66.6.				
	If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.						
4.			ate by which the international preliminary on report must be established according to Rule 69.2 is: 28.10.2004				

Name and mailing address of the international preliminary examining authority:



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1.		to an invitation under Article 14 are referred to in this opinion as "originally	το
	Description, Pages		•
	1-36	as originally filed	

Sequence listings part of the description, Pages

1-10

as originally filed

Claims, Numbers

1-26

3.

as originally filed

Drawings, Sheets

1/13-13/13

as originally filed

These elements were available or furnished to this Authority in the following language:

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

	the language of a translation furnished for the purposes of the international search (under Hule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)).
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	the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
	h regard to any nucleotide and/or amino acid sequence disclosed in the international application, the rnational preliminary examination was carried out on the basis of the sequence listing:
\boxtimes	contained in the international application in written form.
\boxtimes	filed together with the international application in computer readable form.
	furnished subsequently to this Authority in written form.
	furnished subsequently to this Authority in computer readable form.
\boxtimes	The statement that the subsequently furnished written sequence listing does not go beyond the disclosure

The statement that the information recorded in computer readable form is identical to the written sequence

4. The amendments have resulted in the cancellation of:

in the international application as filed has been furnished.

the description,	pages:
the claims,	Nos.:
the drawings,	sheets:

listing has been furnished.

WRITTEN OPINION

International application No.

PCT/CA 03/00964

5.	U	This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).						
6.	Add	dditional observations, if necessary:						
111	. Noi	n-establishment of opinion v	with regard t	to novelty, inventi	ve step and ind	ustrial applicabil	ity	
1.	The obv	he questions whether the claimed invention appears to be novel, to involve an inventive step (to be non- bvious), or to be industrially applicable have not been and will not be examined in respect of:						
		the entire international applic	ation,		,			
	\boxtimes	claims Nos. 1 - 26 (all partiall	y)		-			
		because:						
		the said international applicat not require an international pr	tion, or the sa reliminary ex	aid claims Nos. rela amination (specify)	ate to the followin	ng subject matter v	vhich does	
		the description, claims or draw that no meaningful opinion co	wings <i>(indica</i> ould be forme	ate particular eleme ed (specify):	<i>ents below)</i> or sai	id claims Nos. are	so unclear	
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinic could be formed.					ngful opinio		
	\boxtimes	no international search report	has been e	stablished for the s	aid claims Nos. 1	- 26 (all partially)		
2.	A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:						sting to	
	□.	the written form has not been	furnished or	does not comply v	vith the Standard	l.		
		the computer readable form h	nas not been	furnished or does	not comply with t	he Standard.		
٧.		soned statement under Rule licability; citations and expl				step or industrial		
1.	Stat	ement					•	
	Novelty (N)		Claims	•			•	
	Inve	ntive step (IS)	Claims	1 - 26: No				
	Indu	strial applicability (IA)	Claims			•		
2.	Cita	tions and explanations					•	
	see	separate sheet		•		,	·	



Re Item III No opinion

- In response to an invitation of the ISA to restrict the claims or pay additional 1. search fees the applicant neither restricted the claims nor paid additional fees. Consequently, only invention 1 was searched and the written opinion will also be limited to invention 1.
- The reasons for the non-unity objection were as follows: 2.
 - 2.1 Article 3(4)iii PCT and Rule 13.2 PCT stipulate that where a group of inventions is claimed the requirements of unity shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. "Special" technical features are those features that define a contribution which each of the inventions makes over the prior art.
 - 2.2 The only corresponding technical feature linking the different groups of inventions is that they all relate to genes form Medicago sativa that are allegedly harvest-inducible. Such genes, however, are already known from the prior art (e.g. WO0173090). Therefore, this feature cannot provide a common inventive concept for potential inventions 1 - 3.
 - 2.3 The applicant was requested to note that the alleged function of an gene, i.e. being harvest-inducible, is a non-distinctive characteristic and would not render the subject-matter of claim 1 novel over the prior art.
 - 2.4 Consequently, there is lack of unity, and the different inventions not belonging to a common inventive concept, had been divided into different groups pursuant to Article 17(3)(a) PCT:

Invention 1 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:1), the corresponding regulatory element (SEQ ID NO:4), a method for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous



proteins in plants employing said regulatory element.

Invention 2 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:2), the corresponding regulatory element (SEQ ID NO:5), methods for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Invention 3 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:3), the corresponding regulatory element (SEQ ID NO:6), methods for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D) are referred to; the numbering is following the order of the International Search Report:

- D1 Ferullo et al., 1996. Crop Sci 36:1011-1016.
- D2 Matz and Lukyanov, 1998. Nucl. Acids Res. 26:5537-5543.
- D3 Kuhn, 2001. Ann. Bot. 87:139-155.
- D4 WO-A-0173090 (Samuel Roberts Noble Foundation)

1. Article 33(2)(3) PCT (Novelty and inventive step)

- 1.1 Present claim 1 is directed to method for isolating a harvest-inducible DNA sequence by differential screening.
- 1.2 Document D1 discloses proteins from alflafa that accumulate after harvest and

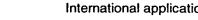


provides an incentive for the isolation of their their cDNAs and the corresponding promoters (page 1016, column 1 2nd paragraph).

- 1.3 A man skilled in the art in need of a method to isolate cDNAs and promoters that are differentially regulated would turn to D2 or D3, both describing strategies for differential screening. He thus would arrive at the subject-matter of present claim 1 without the need for an inventive effort. The same holds true for dependent claim 2 and for claims 4 - 6. Claims 1, 2 and 4 - 6 do not meet the requirements of Article 33(3) PCT.
- 1.4 Present claim 3 is directed to a putative harvest-inducible cDNA sequence consisting of SEQ ID NO:1, fragments thereof or sequences and fragments that hybridise under stringent conditions to SEQ ID NO:1.
- 1.5 It is not apparent form the description that a fragment of SEQ ID NO:1 would solve the technical problem, i.e. the provision of a harvest-inducible cDNA sequence. Present claim 3 does therefore not meet the requirements of Article 33(3) PCT.
- 1.6 The same holds true for present claim 7 directed to a fragment of a harvestinducible regulatory element and for present claims 8 - 26 depending on or relating to claim 7. Claims 3 and 7 - 26 do not meet the requirements of Article 33(3) PCT.

2. Concluding remarks:

- 2.1 The attention of the Applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, Article 34(2)(b) PCT.
- 2.2 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based



WRITTEN OPINION SEPARATE SHEET

(see also Rule 66.8(a) PCT). If the applicant fails to provide these indications the amendments will not be taken into account for the international preliminary examination report

2.3 If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed. Please note that under Rule 11.9 (a) PCT only typed or printed amendments are acceptable.